PATENT SPECIFICATION

(11) 1 274 470

DRAWINGS ATTACHED

1 274 470

(21) Application No. 30330/69 (22) Filed 16 June 1969

(31) Convention Application Nos. 737 637 (32) Filed 17 June 1968
765 608 7 Oct. 1968 in

(33) United States of America (US)

(45) Complete Specification published 17 May 1972

(51) International Classification A61B 17/18

(52) Index at acceptance
A5R X4

(54) IMPROVEMENTS IN OR RELATING TO INTRAMEDULLARY FIXATION DEVICES

(71) I, WILLIAM XAVIER HALLORAN, a citizen of the United States of America, of 440 Fair Drive, Costa Mesa, State of California 92626, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to intramedullary fixation devices.

Intramedullary fixation devices known at present which secure bone fragments from relative transverse movement do not include transverse passages for acceptance of transverse screws for securing compression devices to the exterior of the bone. Intramedullary compression devices have been proposed which include transverse bores for accepting screws, but such devices do not, in themselves, provide support against relative movement of the bone fragments. Devices of this type are shown in U.S. Patent Specification Nos. 2,614,559 and 2,821,979.

In addition, conventional devices usually force an election by the surgeon to provide either intramedullary fixation or compression of the fracture. Since fixation and compression both offer certain advantages, it is desirable to provide a device which effects both. U.S. Patent Specification No. 3,118,444 shows a forearm intramedullary rod having bone-engaging threads on one extremity thereof but does not disclose means for compressing the fracture.

According to the present invention there is provided an intramedullary fixation device for use with a long bone which has been fractured in its medial portion and comprising an intramedullary rod for projecting a substantial distance on either side of the fracture and formed, at least, in its medial portion with a plurality of longitudinally spaced, through slots for receiving screws used to secure a compression plate on the exterior of said bone.

In one embodiment of the present invention the fixation device is characterized by an intramedullary rod which can be installed in the medullary canal to provide support against relative movement of the bone fragments. The rod includes a plurality of longitudinally spaced, through, transverse slots for receipt of screws whereby, either in the initial operation or in a secondary operation, a compression device may be secured to the exterior of the bone to maintain the fracture in longitudinal compression whereby the healing process will be accelerated by both the intramedullary fixation and longitudinal compression of the fracture.

It is preferred that the slots are of sufficient length and number to enable the rod to bend slightly when transverse loads of predetermined force are applied to the mended bone thereby enabling the rod to bend before the bone breaks again. The slots may occupy in excess of 50% of the length of the rod, preferably 80% of the length of the rod.

The rod preferably includes broaching means at one end thereof and may also include a flute extending longitudinally from one end thereof to form a passage for material broached from the medullary canal. Advantageously, the rod includes transverse holes at the inner end of the flute to receive the broached material therefrom.

Depending on the circumstances the rod can be contoured to complement the longitudinal contour of the medullary canal of a radius bone or the longitudinal contour of the medullary canal of a tibia bone.

Another desirable feature is that the device should include means for preventing relative rotation between the bone portions.

The intramedullary fixation device of present invention provides a convenient, practical and sturdy means for fixation and using additional components, to control the amount of compression applied to a fracture. The rod may be utilized as a load-carrying member to prevent direct loading of the fracture and may be utilized to space

the bone portions apart at the fracture site to provide a gap for insertion of bone grafts.

Moreover, it will be apparent that the fixation device of the present invention includes an intramedullary rod which has a substantial portion thereof forming transverse passages for receipt of screws to hold additional fixation or compression elements in place. Said intramedullary rods have sufficient flexibility to enable them to flex slightly when transverse forces are applied to the bone thereby lessening the danger of again breaking the bone. The slots extending transversely through the intramedullary rod provide for communication from one side of the bone to the other thereby enabling bone to grow therein and enhancing the healing rate. Also, the substantial open area provides for receipt of blood and bone pieces to relieve the intramedullary pressure that would otherwise result from build up of such bone pieces and blood and induce healing. Further, after the intramedullary rod is installed the surgeon still retains the option of being able to apply a compression plate to maintain the fracture in longitudinal compression. Still further, the solid circular cross-section of the rod substantially blocks communication longitudinally in the medullary canal thereby preventing the spread of infection and also provides a strong rod which will support weight at an earlier post-operative stage thereby permitting early ambulation and release from the hospital.

To further illustrate the invention and to show how the same may be carried into effect reference will now be made, by way of example to the accompanying drawings in which:—

Figure 1 is an elevational view of a fixation device embodying the present invention;

Figure 2 is an elevational view of second embodiment of the fixation device of the present invention;

Figure 3 is a side view of the fixation device shown in Figure 2;

Figure 4 is an elevational view of a third embodiment of the fixation device of present invention;

Figure 5 is a side view of the fixation device shown in Figure 4;

Figure 6 is an elevational view of a fractured bone which may be maintained in a set condition by the fixation device shown in Figure 1;

Figure 7 is a partially vertical sectioned elevational view similar to Figure 6 depicting the fixation device shown in Figure 1 installed in the fractured bone shown in Figure 6;

Figure 8 is a partly sectioned elevational view of a fractured tibia bone having the fixation device shown in Figure 2 installed therein;

Figure 9 is a partly sectioned elevational view of a radius bone having the fixation device shown in Figures 4 and 5 installed therein;

Figure 10 is a partial side view of the fixation device shown in Figure 1;

Figure 11 is a horizontal sectional view, in enlarged scale, taken along the lines 11—11 of Figure 7;

Figure 12 is a vertical sectional view, in enlarged scale, taken along the lines 12—12 of Figure 11;

Figure 13 is a vertical sectional view, in enlarged scale, taken along the lines 13—13 of Figure 8;

Figure 14 is an elevational view of an intramedullary compression rod embodying the present invention;

Figure 15 is an elevational view of a second embodiment of the intramedullary compression rod shown in Figure 14;

Figure 16 is a vertical sectional view, in enlarged scale, taken along a line 16—16 of Figure 14;

Figure 17 is a horizontal sectional view, in enlarged scale, taken along a line 17—17 of Figure 14;

Figure 18 is a vertical sectional view, in enlarged scale, taken along the line 18—18 of Figure 15;

Figures 19, 20, 21 and 22 are cross-sectional views of modifications of the intramedullary rod shown in Figure 14;

Figure 23 is an elevational view of a femur having the intramedullary rod shown in Figure 14 installed therein; and

Figure 24 is a vertical sectional view taken along the line 24—24 of Figure 23.

Referring now to Figures 1 to 13, a fixation device, generally designated 21, shown in Figure 1 comprises a generally cylindrical rod for installation in the medullary canal of a femur 22 and having a plurality of longitudinally spaced, elongated, through slots 25 therein for receipt of transverse anchor screws 27 (Figure 7). The rod 21 is tapered on its ends and includes broaching grooves 31 whereby the rod can be driven into the intramedullary canal without first reaming out such canal.

The rod also includes a pair of storage passages 35 (Figure 10) at its opposite ends, which passages extend transversely of the slots 25. A pair of oppositely disposed longitudinal flutes 37 extend in from the ends of the rod 21 and terminate at the transverse storage passages 35 whereby broached material may be deposited therein and collected in the storage passages 35 as such rod is driven into the intramedullary canal.

Referring to Figure 7, the rod 21 shown in Figure 1 may be utilized to secure a trans-

verse fracture 41 in a set condition. Rather than merely depending on the rod 21 to maintain the bone fragments fixed relative to one another, a compression plate, generally designated 45, may be secured to the exterior of the bone 22. Referring to Figure 11, the plate 45 is arcuate to compliment the cylindrical shape of the femur bone 22 and includes a plurality of bores for receiving the screws 27. Preferably the screws 27 will project completely through the bone 22 and receive nuts 49 to hold the plate 45 securely in place. The rod 21 is particularly useful as a fixation means where the fracture is of a butterfly type, including a broken-away fragment 54 (Figure 7). The butterfly fragment 53 may be secured in position by a hold-down plate 55 overlying such fragment and secured in position by transverse screws 54. In cases where the rod 21 is installed without a compression plate 45, or hold-down plate 55, a pair of screws 63 should be installed, one above the fracture 41 and one therebelow, to prevent relative rotation between the bone fragments. The elongated slots 25 are preferably of sufficient number and size to render the rod 21 sufficiently rigid to withstand normal loads on the femur but will flex slightly when large transverse forces are put on the femur thereby causing such rod to bend slightly before the forces are sufficient to break the femur again. It has been found that the slots 25 should occupy more than 50% of the length of the rod and preferably 80% of the rod length to ensure that a bore drilled in the femur 22 for the transverse screws 27 will register with one of the slots 25.

The fixation device, generally designated 65, shown in Figures 2 and 3, includes an intramedullary rod having a plurality of transverse passages 67 similar to the passages 25 and such rod is formed with bent ends 71 and 73 to conform the rod to the contour of an average tibia bone 75 (Figure 8). Also, a compression plate 77 may be utilized with the fixation device 65 and may be held in place by a pair of transverse anchor screws 79 disposed above and below a transverse fracture 81 in the tibia 75 to hold such fracture in longitudinal compression. Again, when the rod 65 is used without the compression plate 77, relative rotation of the bone fragments on opposite sides of the fracture 81 is prevented by transverse screws 83 and 85.

The fixation device, generally designated 89, shown in Figures 4 and 5 is similar to the fixation device 21 and includes a plurality of longitudinally spaced elongated slots 91. The rod 89 is formed with a generally curved portion 93 and a straight portion 95 to thereby conform to the longitudinal contour of the intramedullary canal of an average radius bone 97 (Figure 9). Thus the rod 89 may be utilized to secure fragments of a radius bone on opposite sides of fractures 101 and 103 from relative movement. Also, compression plates 105 and 107 may be utilized to hold the fractures 101 and 103, respectively, in longitudinal compression. Again, transverse screws 111 and 113 may be installed to prevent rotation of bone fragments.

In operation, the rod 21 (Figure 7) may be utilized by itself as a fixation device to hold the bone portions 115 and 117 on opposite sides of the fracture 41 from shifting transversely relative to one another. In such case a hole would be bored into one end of the medullary canal and a rod 21 selected having a diameter substantially the same as the medullary canal. The selected rod 21 would then be introduced through said hole and driven into the canal. The broaching grooves 31 eliminate any requirement for reaming the medullary canal before installation of the rod 21. As the rod 21 is driven into the medullary canal, the material broached from the interior of the canal will bunch up at the front of the rod 21 and be received in the flutes 37 (Figure 10). Such broached material will then pass rearwardly in the flutes 37 and be received within the transverse passages 35 extending perpendicular to the passages 25. This serves to prevent such material from bunching up to a considerable degree at the front of the rod 21 and restricting ingress thereof as well as subsequent compacting of such material to subsequently restrict circulation and inhibit healing.

The rod 21 may be utilized by itself as a fixation device and if, at a later date, it is determined that the fracture 41 should be under longitudinal compression, the compression plate 45 may be attached without removal of the rod 21. Such additional secondary operations become necessary because of complications or in situations where the medullary rod 21 breaks. With the rod of present invention the plate 45 may be secured to the exterior wall of the femur 22 without the necessity of removing the rod 21, this capability being of major importance when the patient is not strong enough to withstand an operation to remove the rod 21. This can be accomplished by merely X-raying the femur 22 to determine the orientation of the slots 25 and drilling transverse holes through the bone to allow passage of the screws 27. Thus, the fracture 41 is secured against transverse shifting of the bone fragments as well as being held in longitudinal compression.

It will be clear that, if desired, the compression plate 45 may be installed at the time rod 21 is installed thereby providing the advantages of both an intermedullary rod as well as a compression plate. This

feature is not available when prior art rods are used because they do not have transverse screw receiving slots so the surgeon must elect to either use the rod or the compression plate.

The rod 21 is particularly useful in repairing a fracture resulting in separation of a butterfly fragment 53 (Figure 6). In such a case the rod 21 is installed as described above and a hold-down plate 55 placed over the fragment 53 and screws 54 installed to secure such fragment in position.

The rods 65 and 89 are utilized in substantially the same manner as rod 21 except that they are used as fixation means for the tibia and radius bones respectively.

Referring now to Figures 14 to 24 an intramedullary fixation and compression device shown in Figure 14 includes a rod generally designated 215, having a cross section of sufficient size to substantially fill the cross section of the medullary canal 217 (Figure 24) of the femoral bone B at the site of the fracture 219. The rod 215 also includes a helical groove in its periphery which forms a bone-engaging thread 221 whereby a bore may be drilled in one end of the bone B shown in Figure 23 and the rod 215 inserted therethrough and screwed through the medullary canal of such bone to longitudinally compress the fracture 219.

The rod 215 shown in Figure 14 is intended for use in the medullary canal of a femur B and tapers inwardly from its right hand end 227 to its left hand end 229 to provide a medial diameter 231 which is of substantially the same diameter as the medullary canal 217 (Figure 24) in the area of the fracture 219 whereby transverse shifting of the proximal and distal bone portions 233 and 235, respectively, on opposite sides of the fracture 219 will be prevented.

The rod 215 tapers inwardly at its opposite ends and includes broaching peripheral grooves 241 at its left hand end as shown in Figure 14.

Spaced throughout the length of the rod 215 are a plurality of elongated transverse passages 245 which may be utilized for attachment of an exterior compression plate 246. Such passages further provide for growth of bone from one side of the medullary canal to the other and also offer the capability of draining the medullary canal 217 at the site of the fracture 219.

Referring to Figures 14 and 17, longitudinal grooves 247 are included between adjacent transverse passages 245 to provide an overall longitudinal groove that extends throughout the length of the rod 215 to provide for bone growth longitudinally in the medullary canal 217.

At each extremity of the rod 215 a transverse bore 251, which extends perpendicular to the passages 247, is provided to assist in turning the rod 215 during insertion and retraction from the medullary canal 217. Such bores 251 further receive bone chips from the longitudinal flutes 253 leading in from the ends of the rod 215.

The intramedullary fixation device in Figure 15 includes a rod, generally designated 255, which unlike that shown in Figure 14 has a plurality of helical peripheral grooves included therein for forming threads 257. Further, the rod 255 is of a constant diameter throughout most of its length and, similar to the rod 215, tapers inwardly at its ends and includes broaching grooves 259 at both ends.

The modifications in Figures 19 to 22 are merely optional cross-sections which may be substituted for the circular cross-sections shown in Figures 16 and 18.

In operation the rod 215 is inserted into the medullary canal 217 of the fractured femur B by drilling a bore (not shown) in the proximal end (the right hand end in Figure 23 thereof. The left hand end 229 i.e. the end with the smaller diameter of the rod 215 is then inserted through the bore and into the medullary canal 217. The rod is rotated in a counterclockwise direction, as viewed in Figure 16 to cause the groove 221 to receive the soft cancellous bone 261 (Figure 24) lining the interior of the cortex 263 of the femur B thus affecting a threading action with the medullary canal 217. It will be noted that such threading action avoids scraping the entire cancellous bone 261 of the medullary canal from the cortex 263 thus preserving a portion thereof on the inner wall of the cortex 263 in the area of the fracture 19 to enhance healing of such fracture.

When the leading end 229 of the rod 215 reaches the distal potrion 235 of the femur B, further turning of the rod will draw such portion 235 toward the proximal portion 233 to longitudinally compress the fracture 219. When the rod 215 has been fully inserted into the medullary canal 217, the desired longitudinal compression will be affected on the fracture 219 and, since the medullary canal 217 in the area of the fracture 219 is fully occupied by the rod 215, the bone portions 233 and 235 will be prevented from shifting transversely relative to one another thus maintaining the fracture 219 longitudinally compressed and immobile.

If desired, a compression plate 246 may be secured to the exterior of the femur B by screws 267 extended through elongated passages 245. With the screws 267 inserted the bone portions 233 and 235 will be prevented from rotating relative to one another when weight is put upon the proximal end of the femur B. In situations when the compression plate 246 is not used, trans-

verse screws 269 may be inserted through the bone portion 235 and 233 to prevent relative rotation thereof as the femur B is weighted.

It will be apparent that if a butterfly-type fracture existed or if the bone in the area of the fracture 219 is fragmented or comminuted, the rod 215 will offer the additional advantage of serving as a structural member to carry the weight placed on the proximal bone portion 233. This prevents direct loading of the fracture area 219 and eliminates the danger of telescoping the bone portions 233 and 235 together.

Also in cases where fragments of the bone in the area of the fracture are lost, the bone portions 233 and 235 may be spaced apart to provide a gap at the fracture site 219 for receiving bone grafts.

It is of particular importance that the rod 215 is inserted and removed by a screwing action thus entirely eliminating the necessity of pounding thereon during removal and endangering further bone breakage or refracture.

Operation of the rod 255 shown in Figure 15 is substantially the same as that shown in Figure 14 except that because of its untapered threaded portion, it may be inserted upwardly into the proximal portion 233 from the fracture site 219 and through a bore in the proximal end of the femur B to enable the trailing end to be then screwed downwardly into the distal portion 235. The rod 255 also offers the additional advantage of providing a plurality of spiral thread-forming grooves 257 to affect good purchase in the area of the fracture 219 and leave a greater portion of the cancellous bone 261 undisturbed to further enhance healing.

WHAT I CLAIM IS:—

1. An intramedullary fixation device for use with a long bone which has been fractured in its medial portion and comprising an intramedullary rod for projecting a substantial distance on either side of the fracture and formed, at least, in its medial portion with a plurality of longitudinally spaced, through slots for receiving screws used to secure a compression plate on the exterior of said bone.

2. A fixation device as claimed in Claim 1 wherein the cross section of the medial portion of said rod is of sufficient size to extend substantially across the intramedullary canal in said bone.

3. A fixation device as claimed in Claim 1 or 2, wherein said slots are of sufficient length and number to enable said rod to bend slightly when transverse loads are applied to said bone thereby enabling said rod to bend before said bone breaks again.

4. A fixation device as claimed in any one of the preceding claims wherein said rod includes broaching means at one end thereof.

5. A fixation device as claimed in any one of the preceding claims wherein said rod includes a flute extending longitudinally from one end to form a passage for material broached from said medullary canal.

6. A fixation device as claimed in any one of the preceding claims wherein said rod is contoured to complement the longitudinal contour of a radius bone.

7. A fixation device as claimed in any one of the preceding claims 1 to 5 wherein said rod is shaped to compliment the longitudinal contour of the medullary canal of a human's tibia bone.

8. A fixation device as claimed in any one of the preceding claims 1 to 7 wherein said slots occupy in excess of 50% of the length of said rod.

9. A fixation device as claimed in claim 8 wherein said slots occupy approximately 80% of the length of said rod.

10. A fixation device as claimed in claim 5 or any one of claims 6 to 9 when appendent to claim 5, wherein said rod includes transverse holes at the inner end of said flute to receive said broached material therefrom.

11. A fixation device as claimed in any of the preceding claims and including a compression plate for securement to the exterior of said bone and a plurality of screws for projecting through said slots.

12. A fixation device as claimed in any of the preceding claims wherein said rod is formed with external bone-engaging threads for engaging the walls of said intramedullary canal adjacent the fracture site to maintain the bone fragments on opposite sides of said fracture in fixed relative relationship with respect to one another.

13. A fixation device as set forth in claim 12 wherein said rod is tapered substantially from one end to the other.

14. An intramedullary fixation device substantially as hereinbefore described with reference to, and as shown in the accompanying drawings with the exception of Fig. 6.

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Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1972.
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY
from which copies may be obtained.

1274470 COMPLETE SPECIFICATION

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Sheet 1

FIG.1

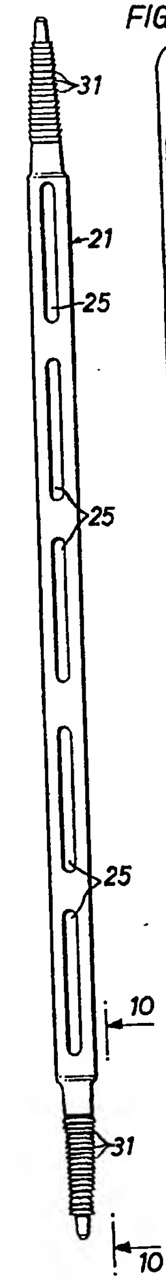


FIG.2

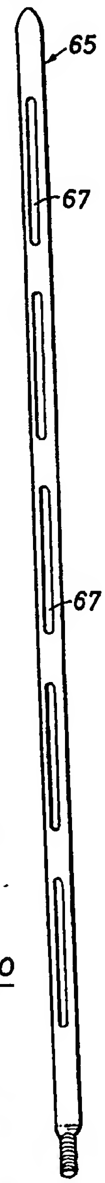


FIG.3

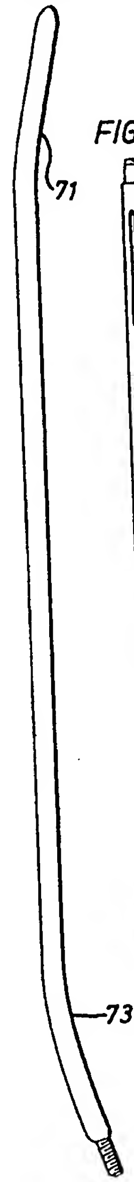


FIG.4

FIG.5

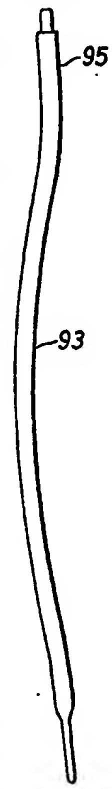


FIG.6

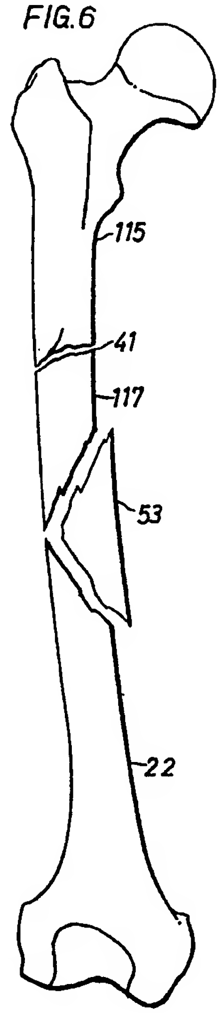


FIG.7

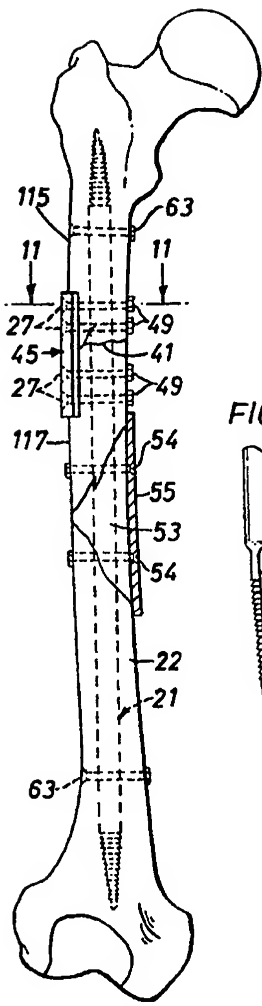


FIG.8

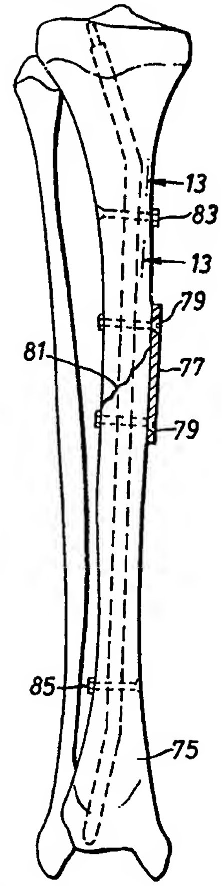


FIG.9

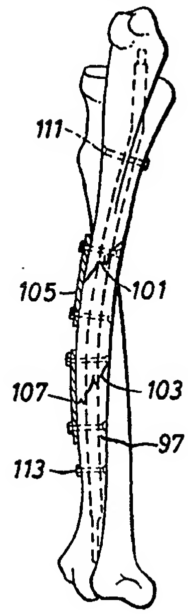


FIG.10

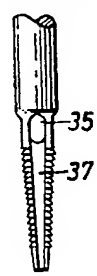


FIG.11

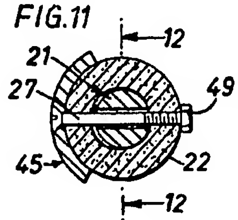


FIG.12

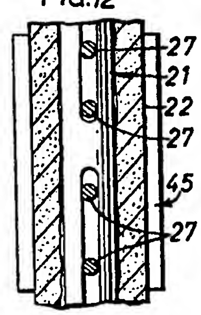
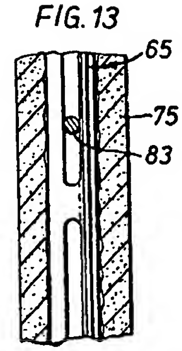


FIG. 13



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Sheet 3

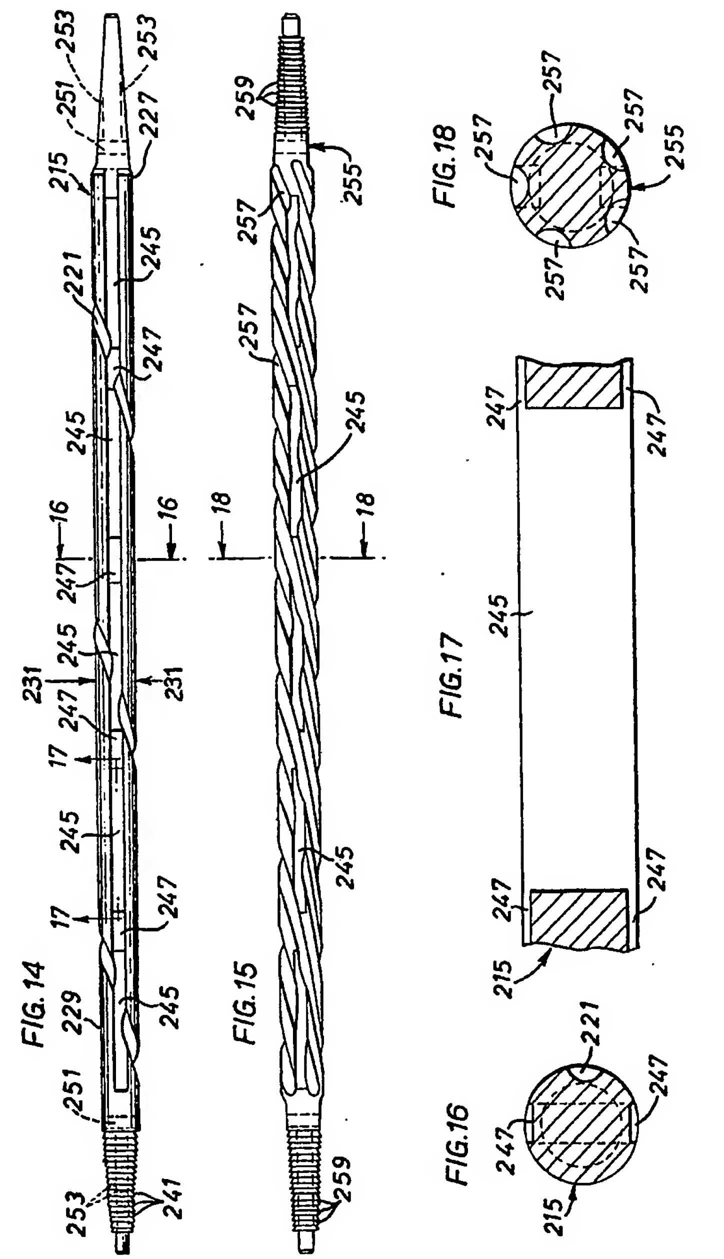

FIG.14 FIG.15 FIG.16 FIG.17 FIG.18

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Sheet 4

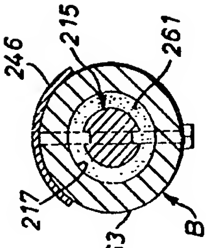

FIG. 24

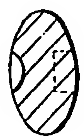

FIG.22

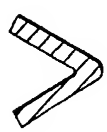

FIG.21

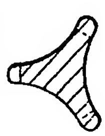

FIG. 20

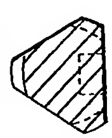

FIG.19

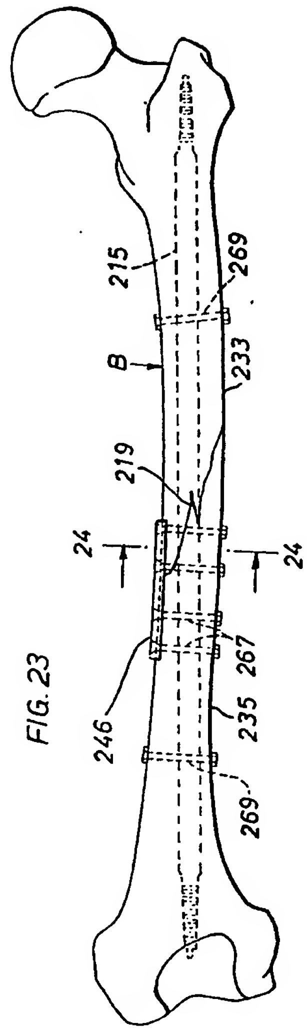

FIG. 23